UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/000,039	12/04/2001	Florian Lang	058315-0135	9721

7590 12/19/2003

Michele M. Simkin
Foley & Lardner, Washington Harbour
Suite 500
3000 K Street, N.W.
Washington, DC 20007-5143

EXAMINER	
MONSHIPOURI, MARYAM	

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 12/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/000,039	LANG ET AL.	
	Examiner	Art Unit	
	Maryam Monshipouri	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 21-38 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) 21-30 and 32-38 is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☒ Claim(s) 31 is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s)
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claims 21-38 are under examination on the merits. Claims 1-20 are canceled.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 23-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "stringent conditions" in claims 23-26 is unclear. Applicant has not defined this term specifically in the specification. In the absence of a clear definition of this term, with respect to salt and temperature conditions used for hybridization, the skilled artisan cannot prepare claimed nucleic acids.

Claims 29-31, and 37-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "immunologically active fragment" in claim 29 and its dependent claims 30-31 and 36-38 is indefinite. Again, applicant has not defined this term in the specification. Hence, the metes and bounds of said term are unclear.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 21-38 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The criteria for undue experimentation, summarized in *re Wands*, 8, USPQ2n 1400 (Fed. Cir. 1988) are: 1) the quantity of experimentation necessary, 2) the amount of direction or guidance presented, 3) the presence and absence of working examples, 4) the nature of the invention, 5) the state of prior art, 6) the relative skill of those in the art, 7) the predictability or unpredictability of the art, and 8) the breadth of the claims.

Claims 32-38 are directed to a pharmaceutical compositions comprising human serum and glucocorticoid kinase (h-sgk) encoding sequences, having SEQ ID NO:2 or specific fragments thereof. It is well known in the art that for any agent to be used as a pharmaceutical composition, an effective dose of that specific agent and the disease/disorder/ condition against which it is used is required. Further when new agents are to be used in a pharmaceutical composition, there is also a need for the demonstration that the agent would be effective in the said dosage against a specific disease/disorder/condition in an art accepted animal model experiment/s. Without such information one skilled in the art would be unable to make and use the claimed invention without undue experimentation. However, in this case the specification fails to provide such details.

The specification does not enable the use of a pharmaceutical composition of h-sgk because the specification does **not** establish/provide :(A)the effective amount of h-

sgk needed for use in a pharmaceutical composition; (B) guidance as to what disease/disorder/condition the pharmaceutical composition is effective against; and (C)demonstrate the desired effect of use in an art recognized animal model experiment.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention drawn to a pharmaceutical composition of h-sgk. Without sufficient guidance, determination of pharmaceutical compositions having the desired characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988) shown above.

Claims 23-26 are further subject to lack of enablement because, the specification fails to teach an assay for "functionally active cell volume-regulated kinase". No examples about the substrates or assays of said kinase are provided either. Current state of prior art indicates that without identifying a specific substrate for cell volume regulated kinase its assay and hence its function remains unclear.

Therefore due to lack of sufficient teachings and examples provided in the specification and due to unpredictability of prior art as to what possibly can be a potential substrate for such a kinase the skilled artisan has to go through the burden of undue experimentation in order to determine the function of the expression products of claimed nucleic acids and as such the claims go beyond the scope of the disclosure.

Similarly, claims 21-22, 27-30, and 32- 37 lack enablement because a DNA sequence comprising a fragment of SEQ ID NO:1 (encoding an immunologically active

polypeptide fragment or otherwise) or comprising only **(a)** 48 (see SEQ ID NO:4) , **(b)** 54 (see SEQ ID NO:3), **(c)** 118 (see claim 27) or **(d)** 500 (see claim 28) bases of that encoding a full-length polypeptide does not comprise enough bases capable of encoding any product with kinase function. Considering *re Wands* factors mentioned above, the specification does not teach about the structural requirements of DNA sequences comprising said number of bases (a)-(d) wherein said DNA sequences encode a product with kinase function. No examples of such DNA sequences are provided either. Current state of the art indicates that for a DNA sequence to encode a product with kinase activity it must comprise at least 750 bases capable of encoding 250 amino acids corresponding to kinase catalytic domain. None of the claimed DNA sequences (see DNA sequences (a)-(d) above) comprise sufficient number of bases to encode a product with kinase function. With respect to DNA sequences comprising fragments of SEQ ID NO:1, the length of the fragments is unknown. Thus, it is possible that many of such claimed DNA sequences are incapable of encoding a product with kinase function.

Therefore, due to lack of sufficient teachings and examples in the specification and due to unpredictability of the prior art about the structural requirements of sequences that comprise said fragments or said DNA sequences (a)-(d) above and encode a product with kinase function, one of skill in the art has to go through the burden of undue experimentation in order to screen for DNA sequences that are within the scope of this invention.

Since claims 21-22, 27-30 lack enablement pharmaceutical compositions comprising said DNA sequences (claims 32-37) lack enablement as well.

Claims 21-22, 27-30, and 32-37 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 29 is directed to a fragment of h-sgk which has been merely defined by function.

The court of Appeals for the Federal Circuit has recently held that such a general definition does not meet the requirements of 35 U.S.C. 112, first paragraph. " A written description of an invention involving chemical genus, like a description of a chemical species, requires a precise definition, such as be structure, formula {or} chemical name, of the claimed subject matter sufficient to distinguish it from other materials." *University of California v. Eli Lilly and Co.,* 1997 U.S. App. LEXIS 18221, at *23, quoting *Fiers v. Revel,* 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). The court held that " in claims involving chemical materials, generic formulae usually indicate with specificity what generic claims encompass. One skilled in the art can distinguish such a formula fro others and can identify many of the species that the claims encompass. accordingly, such a formula is normally an adequate description of the claimed genus. In claims to genetic material, however, a generic statement such as "vertebrate insulin cDNA" or "mammalian insulin cDNA,' without more, is not an adequate written description of the

genus because it does not distinguish it from others. One skilled in the art therefore cannot, as one can do with a fully described genus visualize the identity of the members of the genus". Here, applicant merely claimed the DNA fragments by function wherein said function has not even been clearly specified in the specification, such that it could be distinguished from other fragments. Therefore, based on the information provided the skilled artisan cannot reasonably conclude that applicant had possession of the invention.

With respect to claims 21-22, 27-30, and 32- 37 some structural information about the **genera** claimed DNA sequences are provided but said information is not sufficient to overcome the requirements of 112 first paragraph. This is because a DNA sequence comprising a fragment of SEQ ID NO:1 (encoding an immunoloigically active fragment of otherwise) or comprising only 48 (see SEQ ID NO:4) , 54 (see SEQ ID NO:3), 118 (see claim 27) or 500 (see claim 28) bases of that encoding a full-length polypeptide does not comprise enough bases capable of encoding any product with kinase function. Applicant is well aware that for a DNA sequence to encode a product with kinase activity it must comprise at least 750 bases capable of encoding 250 amino acids corresponding to kinase catalytic domain. None of the claimed DNA sequences comprise sufficient number of bases to encode a product with kinase function. With respect to claims 21-22 and 29 the length of the fragment is not specified and giving the claims the boardest possible interpretation many non-functiuonal species are compruised within the claimed genera of DNA sequences encoding fragments of SEQ ID NO:2.

Thus, considering all said genera, some additional structural information about the claimed DNA sequences is required that is currently lacking in the specification. Applicant merely provided information about a **single species** (namely SEQ ID NO:1) which is insufficient to describe the entire genera as broadly claimed. Again due to aforementioned reasons, the skilled artisan cannot reasonably conclude that applicant had possession of the invention.

Since claims 21-22 and 27-30 lack adequate written description in terms of structure, pharmaceutical compositions comprising them (claims 32-37) also lack adequate written description.

Applicant is referred to the revised interim guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claims 25-26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The phrase "which is not identical to rat sgk" , which is negative limitation in claims 25-26 was searched for explicit support in the specification. However, no support for said phrase could be found. Hence, for examination purposes said phrase is assumed to be **new matter**. Applicant is advised to either direct the examiner to specific page in the specification wherein said limitation is recited or to possibly delete said phrase from aforementioned claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 21-22, 27-29, 30, 32-37 are rejected under 35 U.S.C. 102(b) as being anticipated by Webster et al. (Mol. Cell. Biol., 13, 2031-2040, 1993, cited in the IDS). Webster teaches a DNA sequence encoding rat sgk which has 97.9% homology to SEQ ID NO:2 of this invention. Webster DNA sequence can be considered to be a fragment of SEQ ID NO:1 of this invention and can be considered to comprise: a region encoding amino acid position 313-431 of SEQ ID NO:2, a region comprising bases 980-1480 of SEQ ID NO:1 and a region encoding SEQ ID NO:3, anticipating claims 21-22, 27-30. Webster teaches a rabbit reticulocyte system comprising its rat sgk and said system can be considered to be a pharmaceutical composition comprising a fragment of SEQ ID NO:1, anticipating claims 32-37.

Claims 30 and 37 are rejected under 35 U.S.C. 102(b) as being anticipated by Adams et al. (Nature, 377 (6547suppl), 3-174 , 1995). Adams teaches a DNA fragment encoding an "immunologically active fragment" of h-sgk comprising both SEQ ID NO:3-4 prior to this invention anticipating claim 30 (see the attached sequence alignment). Adams teaches RNA preparation (see page 4) which comprises dissolving said RNA in

a buffer wherein said buffer can be considered to be a comsposition comprising the fragment of claim 30, anticipating claim 37.

Claims 21-37 are rejected under 35 U.S.C. 102(a) as being anticipated by Waldegger et al. (PNAS USA, 94, 4440-4445, April 1997, cited in the IDS). It is noted that applicant claims foreign priority to a German patent. However, applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

In the absence of German patent translation, Waldegger teaches a DNA sequence encoding SEQ ID NO:2. Said sequence can hybridize to SEQ ID NO:1, under stringent conditions and its transcription can neither be induced by serum nor by glucocorticoids, anticipating claims 21-30. Waldegger DNA sequence also comprises the fragments indicated in claims 27-30.

Waldegger also teaches buffers (see for example, page 4441, column 1) comprising all said products and said buffer can be considered to be a pharmaceutical composition comprising said products anticipating claims 32-37.

Allowable Subject Matter

Claim31 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. This is because a DNA fragment consisting of SEQ ID NO:3 or 4 is free of prior art. Further the prior art does not teach or suggest preparing such specifically claimed DNA sequence. Hence said sequence is also non-obvious.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maryam Monshipouri whose telephone number is (703)308-1235. The examiner can normally be reached on 7:00 a.m to 4:30 p.m. except for Alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnanthapu Achutamurthy can be reached on (703)308-3804. The fax phone number for the organization where this application or proceeding is assigned is (703)308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-0196.

MARYAM MONSHIPOURI, PH.D.
PRIMARY EXAMINER

***